U.S.S.N. 09/665,303

Filed: September 19, 2000

AMENDMENT AND

RESPONSE TO OFFICE ACTION

Remarks

Amendment to the Claims

Claims 1-41 are pending. Claims 27-41 have been canceled without prejudice as being

drawn to a non-elected invention.

Claims 1, 8, 11, 16, 17, 18, 19, 20, and 25 were amended to more accurately recite the

claimed devices and methods. These amendments do not narrow, and in some cases actually

broaden, the scope of the claims. The amendments are not being made for reasons of

patentability, as the original claims are believed patentable.

New claims 42-55 have been added. Support for new claims 42-49 is found, for

example, at page 9, lines 1-18. Support for new claims 50 and 51 is found, for example, at page

7, lines 8-13. Support for new claims 52-53 is found, for example, at page 7, line 27 to page 8,

line 7. Support for new claims 54-55 is found, for example, at page 9, line 19 to page 11, line 2.

No new matter has been added. A marked-up version of the amended claim is attached.

The Restriction Requirement and Election

The Office Action divided claims 1-41 into two groups: Group I, claims 1-26, drawn to

an apparatus for drug delivery and a method of using the apparatus; and Group II, claims 27-41,

drawn to a method of making said apparatus. Applicants elect, without traverse, to prosecute

Group I, claims 1-26. New claims 42-55 should be examined with the elected claims.

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Applicants respectfully request examination and allowance of claims 1-26 and 42-55.

Respectfully submitted,

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Version with Markings to Show Changes Made to the Claims

(Once amended) A microchip device for the release of molecules comprising:

 a substrate comprised of two or more substrate portions bonded together[,];
 at least two reservoirs in the substrate, each containing [the] molecules for

release[,]; and

a reservoir cap positioned on, or within a portion of, <u>each of said at least two</u> <u>reservoirs</u> [the reservoir] and over the molecules <u>for release</u>, [so that the molecules are released] <u>the molecules for release being releasable</u> from the device by diffusion through or upon disintegration of the reservoir caps, wherein the release of the molecules from [the] <u>each</u> reservoir is controlled by said diffusion through or disintegration of the reservoir cap <u>positioned</u> thereover.

- 8. (Once amended) The device of claim 1, wherein one of said at least two reservoirs comprises [further comprising a plurality of reservoirs comprising] different types of molecules, different amounts of molecules, or combinations thereof, compared to another of said at least two reservoirs.
- 11. (Once amended) The device of claim [9] 1, further comprising a cathode, a microprocessor, a timer, a demultiplexer, and a power source, wherein at least one reservoir cap is an anode, such that [wherein] upon application of an electric potential between the cathode and anode, said at least one reservoir cap disintegrates[, and exposes the underlying release system to the surrounding fluids] to release the molecules from the reservoir which is under said at least one reservoir cap.

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16. (Once amended) A method for the delivery of molecules comprising:

providing at a site where [the] molecules are to be delivered [the] a microchip device [of claim 1, and] which comprises a substrate comprised of two or more substrate portions bonded together, at least two reservoirs in the substrate, each containing molecules for release, and a reservoir cap positioned on, or within a portion of, each of said at least two reservoirs and over the molecules for release; and

[controlling the release of the] <u>controllably releasing said</u> molecules from <u>each of</u> the reservoir [the reservoir] by said diffusion through or disintegration of <u>each of</u> the reservoir [cap] <u>caps</u>.

- 17. (Once amended) The method of claim 16, wherein the molecules <u>for release comprise a drug</u> [are drugs] and the device is provided at the site by implanting or injecting the microchip into a patient.
- 18. (Once amended) The method of claim 17, wherein the [molecules are a] drug <u>is</u> selected from the group consisting of nucleic acids, proteins, amino acids, polysaccharides, organic molecules, and synthetic molecules.
- 19. (Once amended) The method of claim [18] <u>17</u>, wherein the [drugs are] <u>drug is</u> in combination with a pharmaceutically acceptable carrier.
- 20. (Once amended) The method of claim 16, wherein the molecules <u>for release</u> [are] <u>comprise a diagnostic reagent</u> or <u>a chemical [reagents] reagent</u>.
- 25. (Once amended) The method of claim [23] 16, wherein the device further comprises a cathode, a microprocessor, a timer, a demultiplexer, and a power source, wherein at least one reservoir cap is an anode, and wherein the method further comprises applying an electric potential between the cathode and anode, to [oxidize the reservoir cap and expose the underlying release system to the surrounding fluids] release the molecules from the reservoir under said at least one reservoir cap.

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27-41. (Canceled).

--42. (New) The device of claim 1, wherein the molecules for release comprise drug

molecules.

43. (New) The device of claim 42, wherein the drug molecules are in combination with a

pharmaceutically acceptable carrier.

44. (New) The device of claim 42, wherein the drug molecules comprise a nucleic acid, a

protein, an amino acid, or a polysaccharide.

45. (New) The device of claim 42, wherein the drug molecules comprise a hormone.

46. (New) The device of claim 42, wherein the drug molecules comprise a synthetic, organic

molecule.

47. (New) The device of claim 42, wherein the drug molecules are selected from the group

consisting of anesthetics, vaccines, chemotherapeutic agents, metabolites, immunomodulators,

antioxidants, antibiotics, and ionic channel regulators.

48. (New) The device of claim 1, wherein the molecules for release comprise a diagnostic

reagent or a chemical reagent.

49. (New) The device of claim 48, wherein the molecules comprise a chemical reagent for

use in a polymerase chain reaction or another nucleic acid amplification procedure.

50. (New) The device of claim 1, wherein the molecules for release are in a liquid form.

51. (New) The device of claim 1, wherein the molecules for release are in a solid form.

52. (New) The device of claim 1, which releases the molecules in a pulsatile manner.

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- 53. (New) The device of claim 1, which releases the molecules in a continuous manner.
- 54. (New) The device of claim 1, wherein the reservoir cap comprises one or more polymers.
- 55. (New) The device of claim 1, wherein the reservoir cap comprises a metal thin film.--

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